



# Biotech Daily

Wednesday October 2, 2024

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 7%;  
- MICRO-X DOWN 7%**
- \* **EDITORIAL CLARIFICATION: BIOTECH RECORD CAPITAL RAISINGS**
- \* **FEDERAL \$50m FOR 10 RESEARCH PROJECTS**
- \* **PAT-DX1 'CHALLENGES' SENDS PATRYS TO PAT-DX3**
- \* **ACRUX RECEIVES \$2.7m FEDERAL R&D TAX INCENTIVE; REPAYS LOAN**
- \* **PAINCHEK PREPARES US FDA PAIN APPLICATION**
- \* **ARGENT (MGC) AGM 99.7% SUPPORT ASX DELISTING**
- \* **RADIOPHARM APPOINTS NOEL DONNELLY DIRECTOR**
- \* **INHALERX TO PAY CEO DARRYL DAVIES \$100k SALARY IN SHARES**

## MARKET REPORT

The Australian stock market fell 0.13 percent on Wednesday October 2, 2024, with the ASX200 down 10.7 points to 8,198.2 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell and eight traded unchanged.

Universal Biosensors was the best, up one cent or 6.7 percent to 16 cents, with 326,096 shares traded; followed by Cynata down 6.4 percent to 25 cents with 525,380 shares traded.

Dimerix climbed 4.1 percent; Compumedics and Impedimed improved more than three percent; Medical Developments, Mesoblast, Nova Eye, Paradigm, Prescient and Syntara rose more than two percent; Nanosonics was up 1.4 percent; with 4D Medical, Clarity, Cochlear and Cyclopharm by less than one percent.

Micro-X led the falls, down 0.5 cents or 7.1 percent to 6.5 cents, with 20,647 shares traded.

Alcidion and Curvebeam lost more than six percent; Genetic Signatures was down 5.4 percent; Atomo and Immutep fell more than four percent; Amplia was down 3.3 percent; Aroa, Avita, Emvision, Opthea, Polynovo and Telix shed more than two percent; Neuren, Orthocell and Resmed were down more than one percent; with Clinuvel, CSL and Pro Medicus down by less than one percent.

## [EDITORIAL CLARIFICATION: BIOTECH RECORD CAPITAL RAISINGS](#)

Last night's edition carried two articles claiming difficulties in raising funds in the biotechnology industry.

One said it was a time of "scant investment support in biotechnology" and the other said that "access to funding remains the biggest challenge for start-ups and innovators ... the capital markets, especially when you're at an early stage with your innovation, are particularly tough".

Biotech Daily tabulates all Australian and some New Zealand biotechnology company raisings and, at this stage of the year, we are confident that 2024 will be another record year for capital raisings.

The largest amount ever raised was \$2,182 million in 2021, followed by slightly lower amounts in the subsequent two years.

The sector is on track to exceed the 2021 figure. At June 30, 2024, Australian biotechnology companies had raised more than \$1.5 billion

Full details will appear in the Year In Review in December.

**David Langsam, Editor**

## [FEDERAL GOVERNMENT, NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL](#)

The Federal Government says it will grant \$50 million to 10 research projects through the National Health and Medical Research Council's 2024 synergy grant scheme.

A media release from the Federal Minister for Health and Aged Care Mark Butler said \$5 million would be granted to each project and that recipients included Deakin University for schizophrenia treatments, the University of Melbourne for melanoma immunotherapy and the Walter and Eliza Hall Institute for vaccine development and cancer research.

The Government said the other recipients were Melbourne's Murdoch Children's Research Institute for cardiomyopathy therapies, the University of Newcastle in New South Wales for chronic disease, Melbourne's Monash University for blood transfusion, the University of Sydney for community health, Melbourne's La Trobe University for colorectal cancer and the University of New South Wales for moxidectin research.

The Federal Government said the projects would "will bring together outstanding teams from across health and medical research disciplines to work together to answer major questions that cannot be answered by a single investigator".

Mr Butler said the Government was "investing in Australia's world class researchers to solve some of the hardest problems in health, including the search for a multi-season flu vaccine, better treatment for schizophrenia, and how gut microorganisms may fight off melanoma".

"These \$5 million grants bring together researchers across fields of expertise to answer some of health's most difficult questions," Mr Butler said.

National Health and Medical Research Council (NHMRC) chief executive officer Prof Steve Wesselingh said the grants "provide a special opportunity for highly collaborative teams of diverse researchers to work together to address major problems in human health".

## [PATRYS](#)

Patrys says that manufacturing “challenges”, delays and “potential safety issues” with its PAT-DX1 have caused it to prioritize the development of PAT-DX3 instead.

Last week, Patrys said its contract manufacturing organization expected specification testing for PAT-DX1 to be delayed to the first half of October, following repeated delays starting in 2021, including issues related to purification of the fermentation process resulting in less drug product than expected and “inconsistencies” in another manufacturing process (BD: Aug 3, 2021; Jan 24, 2022; Sep 20, 2024).

Today, the company said its contract development and manufacturing organization had advised its latest batch of PAT-DX1 had met product characterization and specification testing requirements but that “a number of parameters have achieved the threshold levels of acceptance with a narrower margin hat has been observed in the past”.

Patrys said that “given [its] experience with potential product deterioration under long-term storage of PAT-DX1, the company believes that the risk of potential safety issues from using this batch of PAT-DX1 is not acceptable”.

The company said it had “decided it is not appropriate to use this material to initiate a first-in-human, phase I, clinical trial of PAT-DX1 in cancer patients as had been planned”.

Patrys said that due to “the ongoing challenges ... experienced with multiple ... production runs of PAT-DX1, the company is planning to prioritize the development of therapeutic opportunities available for PAT-DX3 for its future [research and development] activities”.

The company said it had produced a stable cell line and master cell bank for PAT-DX3, finalized a production protocol, including upstream fermentation and downstream purification and was “ready for commercial scale production in an engineering run”.

Patrys said it would use “existing data and available drug material to establish co-development and licencing opportunities for PAT-DX1 with partners who have ... expertise and resources to optimize a robust manufacturing process for this challenging molecule”.

Patrys chief executive officer Dr James Campbell said the company believed PAT-DX1 “has great potential for a number of therapeutic applications, the specialized product optimization that has become apparent and which is required to reliably manufacture this unique molecule is better aligned with the resources of larger industry players”.

“This is a disappointment to ... shareholders, the board and management of Patrys,” Dr Campbell said. “However, PAT-DX1 has proven to be a challenging molecule to produce and purify over multiple production runs”.

“We believe it is in the best interest of the company and its shareholders to focus our future development activities and investment on PAT-DX3 rather than PAT-DX1, as we further evaluate other opportunities to advance our deoxymab technology,” he said.

Patrys fell 0.2 cents or 33.3 percent to 0.4 cents, with 53.7 million shares traded.

## [ACRUX](#)

Acrux says it has received \$2,728,021 from the Australian Taxation Officer under the Federal Government’s Research and Development Tax Incentive program.

In June, Acrux said it had a loan of \$1,487,144 from Melbourne’s Radium Capital at 1.33 percent monthly interest against 80 percent of its expected Federal Research and Development Tax Incentive (BD: Jun 28, 2024).

Today, the company said it had used the funds to fully repay its Radium Capital loan, and that its overseas finding application was approved by the Australian Tax Office, granting it additional incentives for eligible overseas expenditure.

Acrux said the incentive related to expenditure for the year to June 30, 2024.

Acrux fell 0.1 cents or 1.85 percent to 5.3 cents.

## [PAINCHEK](#)

Painchek says it has “completed the majority” of requirements for a US Food and Drug Administration application for its facial pain assessment and monitoring application. Painchek said it completed its US clinical validation study for the application in July 2024, which involved 105 volunteers at five aged care homes in Iowa and New York.

The company said data sets had been locked and the performance analysis of the participants completed, with preliminary statistical analysis in the process of being included in the clinical evaluation report.

Painchek said other FDA submission requirements completed for adult approval included US cyber security, software documentation and device labelling requirements that were to be submitted with the clinical evaluation report.

Painchek chief executive officer Philip Daffas said that the US Aged Care market was “the largest in the world where 1,700,000 people reside in these long-term care facilities, with a potential gross annual recurring revenue value of around \$US85,000,000 for Painchek based on our projected US pricing”.

“Should Painchek Adult successfully obtain FDA clearance, Painchek would be the first of its kind FDA-cleared pain assessment tool in the US specifically designed for aged care residents with moderate to severe dementia who are unable to self-report their pain,” Mr Daffas said.

“This clearance would also provide an important predicate for the Painchek Infant [application] and support the expansion of the Adult [application] into larger US markets, including home care and hospitals,” Mr Daffas said.

Painchek was unchanged at three cents.

## [ARGENT BIOPHARMA \(FORMERLY MGC PHARMACEUTICALS\)](#)

Argent says all resolutions at its annual general meeting were passed by more than 99 percent, with 99.69 percent in favor of it delisting from the ASX.

Earlier this year, Argent said investors would vote to delist from the ASX due to a lack of liquidity, fundraising difficulties and costs, and would remain on the London Stock Exchange; as well as issue 4,000,000 shares to managing-director Roby Zomer and 600,000 rights to chair Brett Mitchell (BD: Aug 15, 28, 2024).

Today, the company said the resolution to delist from the ASX was supported by 24,905,052 votes (99.69%), with 78,234 votes (0.31%) against.

Argent said the issue of shares to Mr Zomer, performance rights to Mr Mitchell, the ratification of the prior issue shares and options, as well as the issue of placement shares were all approved by more than 99 percent of the vote.

Argent was up a post-1,000-to-one consolidation half a cent or 0.9 percent to 53.5 cents.

## [RADIOPHARM THERANOSTICS](#)

Radiopharm says it has appointed Noel Donnelly as a non-executive director, effective from October 1, 2024.

Radiopharm said Mr Donnelly had more than 25 years of experience and was currently Pepgen Inc’s chief financial officer, had been EIP Pharma’s chief financial officer and an executive at Takeda/Shire PLC.

The company said Mr Donnelly held a Bachelor of Science from the University of Massachusetts, Lowell and a Master of Business Administration from Boston’s Babson College.

Radiopharm was unchanged at 2.8 cents with 5.0 million shares traded.

## [INHALERX](#)

Inhalerx says its chief executive officer Darryl Davies has agreed to receive 3,444,828 shares in lieu of his \$99,900 salary from February 1 to September 30, 2024.

Inhalerx said the decision was in line with its “cost optimization strategy and prioritization of available capital towards the advancement of its clinical trials of IRX211 and IRX616a.” The company said the price of the shares issued would be calculated based on the 30-day volume weighted average price up-to September 30, 2024, or 2.9 cents.

Inhalerx said the shares were issued under its 15 percent placement capacity, and that, to further prioritize available capital its board had agreed to receive 50 percent of their accrued director fees by issuance of shares, subject to shareholder approval.

Inhalerx was untraded at 3.3 cents.